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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,033	03/26/2004	Scott L. Weinrich	011/007C	9946
22869	7590	10/05/2005	EXAMINER	
GERON CORPORATION 230 CONSTITUTION DRIVE MENLO PARK, CA 94025			SAIDHA, TEKCHAND	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/811,033	<b>Applicant(s)</b> WEINRICH ET AL.	
	<b>Examiner</b> Tekchand Saidha	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

(-)

### DETAILED ACTION

1. Applicants' amendment and response to prior office action, filed August 25, 2005, is acknowledged.
2. Claims 1-25 are pending and under consideration in this examination.
3. Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed as per the amendment cited above have been fully considered but they are not deemed to be persuasive. The reasons are discussed following the rejection(s).

### *New Matter Rejection*

5. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-25 are drawn to a method for producing a compound that regulates telomerase activity. There is no basis in the specification as filed to a 'method of producing a compound.. (claims 1-25)' and method step [for example, claim 1(e) or claim 2(b)], for '...producing the compound if it is identified...'.  
Applicants' arguments:  
Applicants disagree for three reasons. First, all the claims as previously presented were original claims in the application as filed.  
In response, this is not the case. This application is a continuation of US Serial No. 10330872, now US Patent 6787133, there is no basis in the specification of any of the continuing application for the method step "method of producing a compound..". All prior applications have basis for a 'method of

screening inhibitor'. Method of producing a compound, is an additional step not disclosed in the prior applications as filed.

Secondly, Applicants argue that lines 27-29 [which page?] of the substitute specification describes the use of purified telomerase to identify test regulators, inhibitors or activators of telomerase activity *in vitro*. Page 2, lines 30-32 describe how biochemical analysis of the enzyme's mechanism can provide insight for the development of mechanism based regulators. Page 20, lines 28-32 describes telomerase inhibitors and methods of assaying them, incorporating into the specification by reference USSN 08/288,501.

Applicants arguments presented above are irrelevant because these references to pages/lines do not support the undisclosed step '..of a method of producing a compound..' explicitly. One of skill in art screening for specific inhibitor compound(s) of the telomerase activity, would screen known compounds as evidenced by the instant specification (see page 17 or table 1 and page 19). There is no inherent step involved for producing the compound. So the inherency argument extended by the Applicants does not apply. As far as Applicants' incorporating into the specification by reference USSN 08/288,501, such an incorporation is permissible in the application as originally filed. However, this incorporation does not teach the method as claimed.

Table 1, discloses oligonucleotides complementary (antisense) to human telomerase RNA, not the telomerase enzyme activity inhibitor as claimed. Page 17, merely incorporates USSN 08/288,501, by reference, no specific inhibitors are identified in the text. Page 19 has no telomerase inhibitor related information. Thus, no specific 'inhibitors' of the 'telomerase enzyme' is evident or identified. The rejection is therefore maintained.

6. ***Written Description***

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification describes a method of purifying human telomerase protein (200-2000 kDa) from adenovirus-transformed kidney cell line (293 cells), 90-fold and still retaining 29% of the activity (or losing 71% activity) using an oligo-5-affinity column (see Table 4) which can be used to for developing methods to regulate telomerase activity (see Specification, page 3, lines 3-4), thus providing an intent to future development for a method to identify and produce regulators of telomerase without actually describing a single representative species (or method) or having used or disclosed a regulator (inhibitor or activator) of telomerase, let alone produce the same (claims 1-25). There is no disclosure in the method of the size/structure of the mammalian telomerase used or the size/structure of the oligonucleotide used (see for example claims 1-2), other than the range of the molecular weights (200-2000 kDa) of telomerase enzyme containing the RNA component. With such a vague and varying description of a genus it is impossible to establish a relationship among species and claimed genus which uses a entire range of telomerases. Telomerase proteins of various molecular sizes are known. The human telomerase protein is also known to made of distinct subunits, for example, 140 kDa, 105 kDa, 48 kDa and 43 kDa. Telomerases are ribonucleoprotein comprising a protein and an RNA component. There is no description in the specification for (1) a method of identifying a regulator (activator or inhibitor) of telomerase activity, as well as a (2) method for

producing a compound that regulates telomerase activity. Neither a regulator compound has been identified nor a method of producing it has been described in the instant specification. The specification discloses not a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Claims 3-25 have been included in this rejection because they incorporate the broad genus of claims 1 & 2, which remains undescribed.

Applicants' Arguments:

Applicants argue essentially in the same lines as in the previous rejection. Applicants refer to page Table 1, page 17 & page 39, arguing that inhibitors of telomerase were identified.

Table 1, discloses oligonucleotides complementary (antisense) to human telomerase RNA, not the telomerase enzyme activity inhibitor as claimed. Page 17, merely incorporates USSN 08/288,501, by reference, no specific inhibitors are identified in the text. Page 39, gives the level of purification of the telomerase. Thus, no specific 'inhibitors' of the 'telomerase enzyme' is evident or identified.

See University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CAFC 2004), wherein, "A method patent for treating the side effects of pain relievers is invalid for failing to adequately describe the compound used in the claimed method, the U.S. District Court for the Western District of New York rules. Granting a summary judgment motion, the court reasons that the written description requirement of 35 U.S.C. §112 ¶1 cannot be satisfied by merely providing the desired function of the compound without more detail on the

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compound's structure, chemical formula, chemical name, or physical properties. The court also stresses the applicability of the written description requirements to the compound used, even though the patent consists of method claims rather than compound claims.

7. The double patenting rejection made in the prior Office Action is hereby withdrawn as the claims are not directed to 'a method of producing a compound..', and in view of the arguments presented by the Applicants.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

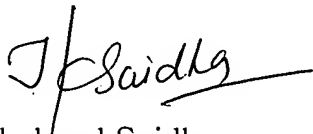
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272

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0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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September 30, 2005